General

Guideline Title

Transrectal ultrasound guided biopsy of the prostate.

Bibliographic Source(s)

Turner B, Aslet Ph, Drudge-Coates L, Forristal H, Gruschy L, Hieronymi S, Mowle K, Pietrasik M, Vis A. Transrectal ultrasound guided biopsy of the prostate. Arnhem (The Netherlands): European Association of Urology (EAU); 2011 Mar. 52 p. [84 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 12, 2016 – Fluoroquinolone Antibacterial Drugs : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Levels of evidence (LE) (1a-4) and grades of recommendation (GR) (A-C) are defined at the end of the "Major Recommendations" field.

Transrectal Ultrasound (TRUS) and Biopsy Procedure

Patient Preparation

- Caution has to be observed in patients on steroid medication as it has been shown to be a risk factor for sepsis (Aus et al., 1993) (LE=3, GR=C)

- Cleansing enema before biopsy provides no clinically significant outcome advantage, and potentially increases patient cost and discomfort and is therefore not recommended. (Carey & Korman, 2001) (LE=1b, GR=C)
- Low dose aspirin is not considered a contraindication to biopsy (Giannarini, et al., 2007). (LE=1b)
- Broad spectrum antibiotic use is common practice but guidelines should be made locally in consultation with microbiology advice (Heidenreich et al., 2010; Aron, Rajeev, & Gupta, 2000; Feliciano et al., 2008). (LE=3, GR=B)
- Patients at risk of endocarditis should be considered for prophylaxis (Siegman-Igra, 2010). (LE=3, GR=C)
- Where possible single use equipment should be used, particularly single use needle guides to reduce the risk of infection (Tuncel et al., 2008). (LE=1, GR=B-C)

Consent

- It is recognised as good practice to get written consent. (LE=4, GR=C)
- The patient should be informed of any risk factors specific to them. (LE=4, GR=C)

Prostate Biopsy

- The diagnosis of prostate cancer should be based on histopathological confirmation. (GR=B)
- Biopsy and further staging investigations are only indicated if they affect patient management. (GR=C)
- TRUS guided systematic biopsy is the recommended method in suspected prostate cancer (An abnormal digital rectal examination (DRE) or a raised prostate specific antigen (PSA) are indications for prostate biopsy) (GR=B)
- Peri-prostatic local anaesthetic injection should be offered as analgesia when undergoing biopsy. (GR=A)
- A minimum of 8 laterally directed biopsy cores are recommended. (GR=B)
- One set of repeat biopsies are recommended in cases with persistent indication. (GR=B)
- More than 2 transrectal biopsies for persistent indication cannot be recommended. (GR=C)

Complications and Their Management

Patient Information on Discharge

- Ensure that the patient understands the potential complications of the procedure and what he must do in case of fever, infection, clot retention, urinary retention or persistent bleeding and who to contact. (LE=4, GR=C)
- Patients should be advised on rest, fluid intake, prophylactic antibiotics and follow-up. (LE=4, GR=C)
- Patients with urethral catheter should be closely monitored for signs of sepsis. (LE=2a, GR=B-C)
- Patients with diabetes mellitus should be closely monitored for signs of sepsis. (LE=2a, GR=B-C)

Knowledge and Understanding

Skills Acquisition and Development

- Health care professionals undertaking prostate biopsies should be trained by a competent practitioner. (LE=4, GR=C)
- Health care professionals undertaking prostate biopsies should be trained in physical assessment including digital rectal examinations. (LE=4, GR=C)
- Health care professionals undertaking prostate biopsies should have at least 3 years experience in working with prostate cancer patients. (LE=4, GR=C)
- Health care professionals undertaking prostate biopsies should be registered practitioners and carry liability insurance. (LE=4, GR=C)
- Health care professionals are deemed competent after performing a minimum of 20 biopsies satisfactorily without supervision at an acceptable speed. (LE=4, GR=C)
- Direct supervision should be undertaken until the health care professional is deemed competent to undertake the procedure independently. (LE=4, GR=C)
- Final competence should be assessed and signed by a senior urologist. (LE=4, GR=C)
- Health care professionals are required to keep current of the latest advances in the field for which they should be a member of a professional organization and follow continuing education. (LE=4, GR=C)

Definitions:

Level of Evidence

1a Evidence obtained from meta-analysis of randomised trials

1b Evidence obtained from at least one randomised trial

2a Evidence obtained from one well-designed controlled study without randomisation

2b Evidence obtained from at least one other type of well-designed quasi-experimental study

3 Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports

4 Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Grade of Recommendation

A Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial

B Based on well-conducted clinical studies, but without randomised clinical trials

C Made despite the absence of directly applicable clinical studies of good quality

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Prostate cancer

Guideline Category

Diagnosis

Evaluation

Management

Clinical Specialty

Nursing

Surgery

Urology

Intended Users

Advanced Practice Nurses

Nurses

Guideline Objective(s)

- To enhance urological nursing practice and assist the professional development of the individual in the development and provision of transrectal ultrasound guided (TRUS) prostate biopsy ensuring patient safety, dignity and comfort, and the delivery of the highest quality

patient care
- To support practitioners who are already assessed as competent in TRUS

Target Population

Men with suspected prostate cancer

Interventions and Practices Considered

1. Patient preparation
    - Assessment of risk factors
    - Antibiotic prophylaxis
    - Single use equipment
2. Transrectal ultrasound guided prostate biopsy
    - Minimum of 8 laterally directed biopsy cores
    - Repeat biopsies, as indicated
3. Histopathological assessment of biopsy tissue
4. Peri-prostatic local anaesthetic injection
5. Patient discharge and follow-up: provision of information to patient regarding potential complications
6. Post procedure patient monitoring
    - Patients with urethral catheter
    - Patients with diabetes
7. Training of professionals

Note: Performing more than 2 transrectal biopsies for persistent indication was considered but not recommended.

Major Outcomes Considered

- Incidence of prostate cancer
- Side–effects/complications of transrectal guided prostate biopsy

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

The information offered in this guideline was obtained through a systematic literature search and through review of current procedures undertaken in various member countries of the European Association of Urology Nurses (EAUN). All group members participated in the critical assessment of the scientific papers identified. Bibliographical databases consulted included EMBASE, Medline and the Cochrane Library database CENTRAL. The search was based on the keywords (listed below). Both EMBASE and Medline were searched using both 'Free text' and the respective thesauri MesH and EMTREE. The time frame covered in the searches was January 2000 to September 2010.

Limitations of the Search

In Medline and EMBASE the search results were limited to randomised controlled trials (RCTs), in CENTRAL to controlled clinical trials. In all databases, output was limited to human studies and English language publications.

Search Keywords

The reference search included the following key words (in alphabetical order):

- Antibiotic
- Biopsy
- Cancer
- Ciprofloxacin
- Doppler
- Infectious
- Competency
- Complication
- Consent
- Digital rectal examination
- Examination
- Guideline
- Histology
- Leucocytes
- Lidocaine
- MRI
- Nitrates
- Patient education
- Prophylaxis
- Prostate
- Prostate biopsy
- Prostate cancer
- Prostatic neoplasms
- PSA
- Safety
- Training requirements
- Transrectal
- Transrectal ultrasound and prostate biopsy
- TRUS
- Ultrasound
- Vascularity
- Volume

Search Results

The European Association of Urology Nurses (EAUN) commissioned a company to do an initial search on TRUS, ultrasound, prostate and biopsy which resulted in a total of 477 scientific publications (312 papers in CENTRAL and 165 in EMBASE/Medline).

An additional search focusing on infectious complications and increased volume of the prostate gave 40 level 1 publications but none of them proved relevant to this guideline. Two group members made a selection of the most relevant abstracts for this document. It was a policy decision to restrict the search in this way, though the group were aware that more complex strategies were possible, and would be encouraged in the context of a formal systematic review.

Number of Source Documents

An initial search on TRUS, ultrasound, prostate and biopsy resulted in a total of 477 scientific publications (312 papers in CENTRAL and 165 in EMBASE/Medline).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

1a Evidence obtained from meta-analysis of randomised trials

1b Evidence obtained from at least one randomised trial

2a Evidence obtained from one well-designed controlled study without randomisation

2b Evidence obtained from at least one other type of well-designed quasi-experimental study

3 Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports

4 Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Methods Used to Analyze the Evidence

Review

Review of Published Meta-Analyses

Description of the Methods Used to Analyze the Evidence

The recommendations provided in these documents are based on a rating system modified from that produced by the Centre for Evidence-based Medicine (see the "Rating Scheme for the Strength of the Evidence" field).

Some of the literature was not easy to grade. If, however, the EAUN working group thought the information would be useful in practice, it is ranked as level of evidence 4 and grade of recommendation C.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guidelines working group consisted of a multi-professional group of specialist nurses and a medical colleague.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

A Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial

B Based on well-conducted clinical studies, but without randomised clinical trials

C Made despite the absence of directly applicable clinical studies of good quality

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Prior to publication, blinded review was carried out by 8 reviewers. Involved were nurse specialists, urologists, an oncological pathologist and an oncologist. After discussion of all comments received, appropriate revisions were made by the working group and the document was approved by the European Association of Urology Nurses (EAUN) Board and the European Association of Urology (EAU) Executive Board member responsible for EAUN activities.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Aron M, Rajeev TP, Gupta NP. Antibiotic prophylaxis for transrectal needle biopsy of the prostate: a randomized controlled study. BJU Int. 2000 Apr;85(6):682-5. PubMed

Aus G, Hermansson CG, Hugosson J, Pedersen KV. Transrectal ultrasound examination of the prostate: complications and acceptance by patients. Br J Urol. 1993 Apr;71(4):457-9. PubMed

Carey JM, Korman HJ. Transrectal ultrasound guided biopsy of the prostate. Do enemas decrease clinically significant complications. J Urol. 2001 Jul;166(1):82-5. PubMed

Feliciano J, Teper E, Ferrandino M, Macchia RJ, Blank W, Grunberger I, Colon I. The incidence of fluoroquinolone resistant infections after prostate biopsy--are fluoroquinolones still effective prophylaxis. J Urol. 2008 Mar;179(3):952-5; discussion 955. PubMed

Giannarini G, Mogorovich A, Valent F, Morelli G, De Maria M, Manassero F, Barbone F, Selli C. Continuing or discontinuing low-dose aspirin before transrectal prostate biopsy: results of a prospective randomized trial. Urology. 2007 Sep;70(3):501-5. PubMed

Heidenreich A, Bolla M, Joniau S, et al, members of the European Association of Urology (EAU) Guidelines Office. Guidelines on prostate cancer. In: EAU Guidelines, edition presented at the 25th EAU Annual Congress. Barcelona (Spain): European Association of Urology (EAU); 2010.

Siegman-Igra Y. Infective endocarditis following gastrointestinal and genitourinary procedures: an argument in favour of prophylaxis. Scand J Infect Dis. 2010 Mar;42(3):208-14. PubMed

Tuncel A, Aslan Y, Sezgin T, Aydin O, Tekdogan U, Atan A. Does disposable needle guide minimize infectious complications after transrectal prostate needle biopsy. Urology. 2008 Jun;71(6):1024-7; discussion 1027-8. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of patients undergoing transrectal ultrasound guided biopsy of the prostate

Potential Harms

Complications associated with transrectal ultrasound guided prostate biopsy including:

- Minor complications (haematuria, haematospermia, blood in the stools, dysuria, rectal bleeding, prostatitis, epididymitis)
- Severe complications (urosepsis, septicaemia, urinary or clot retention, severe rectal bleeding)

Qualifying Statements

Qualifying Statements

Limitations of Document

The European Association of Urology Nurses (EAUN) acknowledge and accept the limitations of this document. Guidelines provide a standardised approach to patient care and management and the practitioner must tailor care towards the individual patient. Their aim is to help healthcare professionals to make informed decisions about their patients. Adherence to a guideline does not guarantee a successful outcome. Ultimately, healthcare professionals must make their own decisions about care on a case-by-case basis, using their clinical judgement, knowledge and expertise, and after consultation with their patients. Therefore these guidelines provide recommendations without legal implications.

Cost-effectiveness considerations and non-clinical questions are best addressed locally and therefore fall outside the remit of these guidelines. Other stakeholders, including patient representatives, have not been involved in producing this document.

This guideline discusses transrectal ultrasound and prostate biopsy. Transperineal biopsy is not addressed. When high quality publications were lacking, the recommendations were based on expert reports or expert consensus. This is clearly indicated in the document.

Limitations

This guideline is limited to transrectal ultrasound (TRUS) biopsy and does not include TRUS guided transperineal biopsy although the working group recognises that this approach is becoming more widely used and it may be addressed in a future document.

These guidelines should be used within the context of local policies and existing protocols. It is acknowledged that throughout Europe nurses in different countries have different levels of involvement; some undertake the procedure independently whilst others assist medical colleagues. Additionally, it is acknowledged that there is wide variation in nursing titles: for the purpose of this document the term 'specialist nurse' will be used.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Mar

Guideline Developer(s)

European Association of Urology Nurses - Medical Specialty Society

Source(s) of Funding

European Association of Urology

Printing and distribution of this guideline was made possible through educational grants supplied by Novartis, Amgen and AstraZeneca.

Guideline Committee

European Association of Urology Guidelines Working Group

Composition of Group That Authored the Guideline

Working Group Members: B. Turner, Ph. Aslet, L. Drudge-Coates, H. Forristal, L. Gruschy, S. Hieronymi, K. Mowle, M. Pietrasik, A. Vis

Financial Disclosures/Conflicts of Interest

All members of the European Association of Urology Nurses (EAUN) guidelines working group have provided disclosure statements of all relationships that might be a potential source of conflict of interest. The information has been stored in the EAU(N) database.

The EAUN is a not for profit organisation and with the exception of administrative assistance, travel and meeting expenses, no honoraria or other reimbursements have been provided. Printing and distribution of this guideline was made possible through educational grants supplied by Novartis, Amgen and AstraZeneca. Industry representatives have had no influence on working group composition, content selection nor have they been included in the (blinded) review process prior to publication.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the European Association of Urology Nurses (EAUN) Web site .

Print copies: Available from the European Association of Urology (EAU), PO Box 30016, NL-6803, AA ARNHEM, The Netherlands. E-mail: eaun@uroweb.org and from the EAU webshop .

Availability of Companion Documents

The following is available:

- TRUS guided biopsy of the prostate – training document. 5 p. Electronic copies: Available from the European Association of Urology Nurses Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on October 18, 2011. The information was verified by the guideline developer on November 28, 2011. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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